UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,481	06/23/2003	Andrew Fensome	AHPWA25AUSA	8944

38199 7590 04/01/2005

HOWSON AND HOWSON
CATHY A. KODROFF
ONE SPRING HOUSE CORPORATE CENTER
BOX 457
SPRING HOUSE, PA 19477

EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,481	FENSOME ET AL.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,14 and 25-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 14, 25-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 1-11, 14 AND 25-40 ARE PRESENTED FOR EXAMINATION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submissions filed on December 3, 2004 and February 8, 2005 have been entered. Accordingly, claims 12, 13, 15 and 16 have been canceled; claims 1, 8 and 28 have been amended; and claims 29-40 have been added.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 35-40 set forth "phases" and/or a time period, in days, wherein certain agents, either active or a placebo, are administered for the purpose of achieving the objective of providing a contraceptive regimen. The phases and time periods, however, have not been presented in the manner as present in the specification as originally filed. In particular, the

present claims fail to relate the claimed periods of time or phases in a sequential or any manner and thus the claims encompass instances of administration where such periods of time or phases may be concurrent or else unrelated to one another. This concept of concurrent or unrelated administration is a concept that was not disclosed in the specification as originally filed and thus represents new matter.

As an illustration of where the periods of administration are unrelated and thus may be concurrent, claim 35 is referenced. This claim reads:

> 35(New). The regimen according to claim 33, wherein said regimen comprises:
>
> (a) delivering said compound of formula I or formula II and said selective estrogen receptor modulator for 14 to 24 days; and
>
> (b) delivering said selective estrogen receptor modulator for 1 to 11 days.

Here, because the claim simply reads "for 14 to 24 days" in section (a) and "for 1 to 11 days" in section (b), there lacks a defining relationship between the time periods, such that an instance where the "for 1 to 11 days" of (b) may be a period of time, e.g., a period of 9 days, within the period of "for 14 to 24 days" of (a). This concept does not appear in the specification as originally filed.

Rather, the specification as originally filed at pages 34-36 teaches that where the treatment regimen, whether it be a 21-, 28-, 30- or 31-day cycle, includes the administration of multiple active agents, each having a defined administration period, such periods are defined in such a manner that it is clear that there is a relationship between the administration periods. For example, in the specification as originally filed, it is set forth at page 35, lines 13-16 that

In a further embodiment, the compounds of formula I and/or formula II are delivered with the SERM for the first 14 to 24 days of a 28-day cycle, followed by delivery of the SERM alone for a period of 1 to 11 days beginning on any cycle day between day 14 and 24.

Thus, from the specification as originally filed, the concept that the compounds of formula I and/or formula II are delivered with the selective estrogen receptor modulator ("SERM") "for the first 14 to 24 days of a 28 day cycle, followed by delivery of the SERM alone for a period of 1 to 11 days beginning on any cycle day between day 14 and 24" (emphasis added) was present. Present claims 35-40 lack any reference to a relationship between the time periods or phases of administration and such represents a concept that was not present in the specification as originally filed, i.e., new matter.

As a further example, claim 36, which depends from the above cited claim 35 sets forth:

"36(New) The regimen of claim 35, wherein said regimen further comprises

(c) delivering a placebo for 1 to 10 days.".

The specification as originally filed, however, contains no such unrestricted disclosure for the instance where the regimen includes the administration of a placebo. Instead, the specification as originally filed contains concise instructions for administration of the placebo which includes, unlike claim 36, a reference to the administration period of the active agents. In particular, it is set forth at page 33 of the specification, lines 11-15 that:

" Such periodic discontinuation can include delivery of a placebo during the period of time where the composition of the invention or SERMS are not delivered to the patient. Alternatively, no placebo or active agent is delivered to the patient when the compositions and SERMS are not being delivered to the patient."(emphasis added).

The above disclosure in the specification as originally filed also fails to provide support for the requirements in present claim 39 where (i) the SERM is administered on "days 1 to 11 of said regimen" and the placebo is administered "for days 1 to 10 of said regimen", i.e., where both the placebo and active agents may be administered during the same period of time, or for (ii) "a third phase in which component (a) or (b) is not administered for days 1 to 10 of said regimen", i.e., claim 39 specifically requires in (b) that "said selective receptor modulator to be administered on days 1 to 11 of said regimen" which is a required step, but which would not be a possibility if "component (a) or (b) is not administered for days 1 to 10 of said regimen.".

Also, only at page 33, lines 13-15 of the specification is the Examiner able to locate a teaching which is indicative of a period of time where no placebo or active agent is delivered to the patient when the compositions and SERMS are not to be delivered to the patient. Such does not indicate, however, that such a period takes place "for days 1 to 10 of said regimen" as in present claim 39. Applicants should point out where in the specification as originally filed one may find the concept of part (c) of claim 39, i.e., "a third phase in which component (a) or (b) is not administered for days 1 to 10 of said regimen".

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Considering the teachings provided in the specification as originally filed, the Examiner finds that Applicants have failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures,

diagrams and formula that fully set for the invention as is now present in claims 35-40, in such a way as to reasonably convey to one skilled in the relevant art that Applicants had possession of the concept of a contraceptive regimen wherein the periods of administration for the active agents therein are without any type of defined relationship.

In order to overcome the present rejection, it is suggested that Applicants adopt the specific language as employed in the present specification at pages 34-36, where a particular relationship is set forth for the periods of administering the agents.

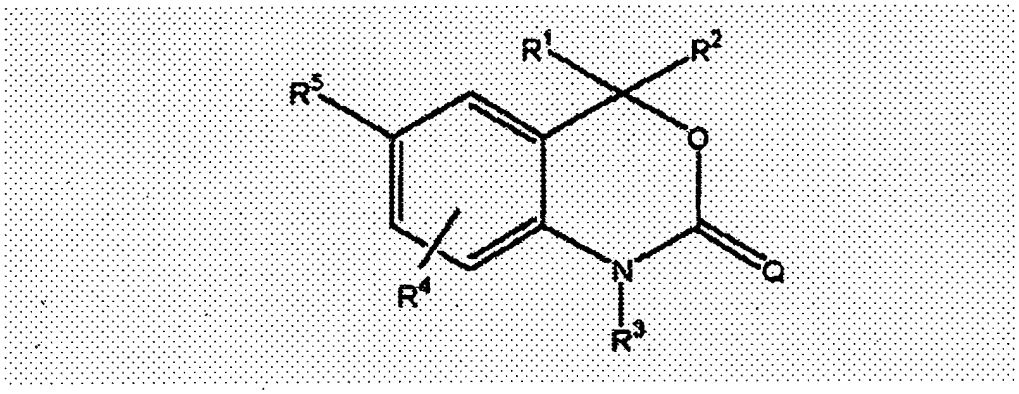
Claim Rejection - 35 USC § 103

Claims 1-11, 14 and 25-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/66570 and applicants' acknowledgment at page 4, lines 3-5 of the present specification in view of Gast et al. (U.S. Patent Application Publication No. 2002/0061875), each of record, for the reasons of record as set forth in the previous Office action dated September 8, 2004 at pages 2-3, as applied to claims 1-16 and 25-28.

Claims 37-40 are not taught or suggested by references relied on and thus are not subject to the present rejection.

Respecting claims 1-11, 14 and 25-28, such remain properly rejected because, while applicants have limited the scope of the compounds in claims 1, 8 and 28, these compounds are generally provided for by the '570 reference at pages 7-19. For example, where in formula I where (i) R^1 and R^2 may be "H, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_2 to C_6 alkenyl, C_3 to C_8 cycloalkyl, phenyl, and thiophene or R^1 and R^2 are fused to form a carbon-based 3 to 8 member saturated spirocyclic ring is taught in the '570 reference at page 7, lines 8-15 and in the examples; (ii) R^3 is H may be found in the '570 reference at page 8, line 1; (iii) R^4 is H may be

found in the '570 reference at page 8, line 7; and (iv) that R^5 may be as defined in the present claims may be found in the '570 reference at page 8, line 10 – page 9, line 8. The present definition of the compound of formula II wherein X, Y, Z are as defined may be found in the '570 reference at page 10 wherein in the general formula of:



R^5 may be a pyrrole moiety which is monosubstitued by a cyano group (page 15, lines 15-23); R^4 may be H (page 15, line 7); R^3 may be H (page 15, line 5); and R^1 and R^2 may be independently be selected from a C_1 to C_6 alkyl or a substituted C_1 to C_6 alkyl wherein the alkyl may be from 1-3 carbon atoms, e.g., methyl, ethyl, propyl, (page 13, lines 3-4) and "substituted" included halogen (page 18, line 10).

Newly added claims 29-36 are properly included because claims 29-31 and 33 contain no further limitations than those already considered. Gast teaches that:

"The vast majority of oral contraceptives consist of a combination of a progestin and estrogen that are administered concurrently for 21 days followed either by a 7 day pill free interval or by the administration of a placebo for 7 days in each 28 day cycle." (page 1, paragraph [0003]).

Thus, Gast suggests the administration of a placebo or a pill free period that lasts for 7 days as encompassed by present claims 32 and 36. Also, because Gast highlights the

administration of the combination of agents "for 21 days", such would meet the requirements of present claims 34 and 35. Claim 35 is deemed properly included because it appears from the manner in which the claim has been worded that section (b) may be included in section (a) and thus the administration of step (a), which requires "for 14 to 24 days", would encompass the 21 days as suggested by Gast.

Applicants' arguments at page 17 of their most recently filed amendment have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

Applicants have merely taken the position that the present claims are patentable because neither of the references relied on above teach or suggest the presently claimed subject matter, in particular that the present compounds that are now set forth in the claims are not taught or suggested. Such arguments, however, fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

The Examiner has pointed to page and line of the references relied on to support the conclusion that the presently claimed subject matter would have been obvious.

Accordingly, the claims are deemed properly rejected.

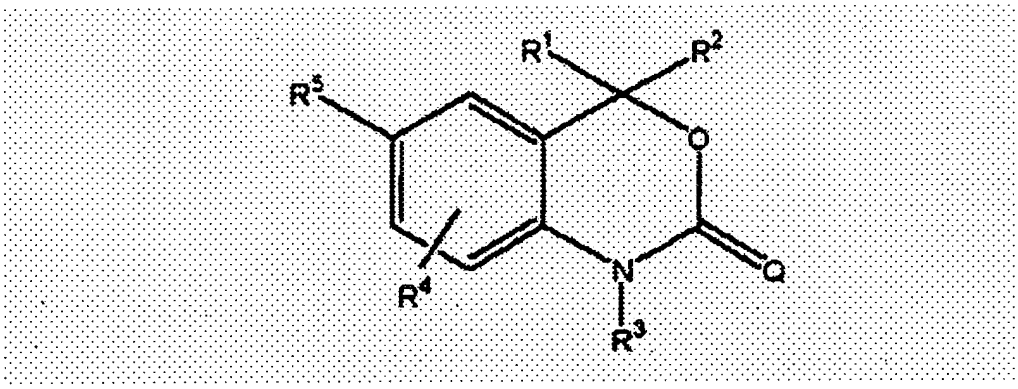
Double Patenting

Claims 1-11, 14 and 25-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 91 and 92 and each of the claims directly and indirectly upon which they depend of U.S. Patent No. 6,436,929 in view of WO'570 and Gast et al. (U.S. Patent Application Publication No. 2002/0061875), each of record,

for the reasons of record as set forth in the previous Office action dated September 8, 2004 at pages 3-4, as applied to claims 1-16 and 25-27.

Claims 37-40 are not taught or suggested by references relied on and thus are not subject to the present rejection.

Respecting claims 1-11, 14 and 25-28, such remain properly rejected because, while applicants have limited the scope of the compounds in claims 1, 8 and 28, these compounds are generally provided for by the '570 reference at pages 7-19. For example, where in formula I where (i) R^1 and R^2 may be "H, C_1 to C_6 alkyl, substituted C_1 to C_6 alkyl, C_2 to C_6 alkenyl, C_3 to C_8 cycloalkyl, phenyl, and thiophene or R^1 and R^2 are fused to form a carbon-based 3 to 8 member saturated spirocyclic ring is taught in the '570 reference at page 7, lines 8-15 and in the examples; (ii) R^3 is H may be found in the '570 reference at page 8, line 1; (iii) R^4 is H may be found in the '570 reference at page 8, line 7; and (iv) that R^5 may be as defined in the present claims may be found in the '570 reference at page 8, line 10 – page 9, line 8. The present definition of the compound of formula II wherein X, Y, Z are as defined may be found in the '570 reference at page 10 wherein in the general formula of:



R^5 may be a pyrrole moiety which is monosubstitued by a cyano group (page 15, lines 15-23); R^4 may be H (page 15, line 7); R^3 may be H (page 15, line 5); and R^1 and R^2 may be

independently be selected from a C_1 to C_6 alkyl or a substituted C_1 to C_6 alkyl wherein the alkyl may be from 1-3 carbon atoms, e.g., methyl, ethyl, propyl, (page 13, lines 3-4) and "substituted" included halogen (page 18, line 10).

Newly added claims 29-36 are properly included because claims 29-31 and 33 contain no further limitations than those already considered. Gast teaches that:

"The vast majority of oral contraceptives consist of a combination of a progestin and estrogen that are administered concurrently for 21 days followed either by a 7 day pill free interval or by the administration of a placebo for 7 days in each 28 day cycle." (page 1, paragraph [0003]).

Thus, Gast suggests the administration of a placebo or a pill free period that lasts for 7 days as encompassed by present claims 32 and 36. Also, because Gast highlights the administration of the combination of agents "for 21 days", such would meet the requirements of present claims 34 and 35. Claim 35 is deemed properly included because it appears from the manner in which the claim has been worded that section (b) may be included in section (a) and thus the administration of step (a), which requires "for 14 to 24 days", would encompass the 21 days as suggested by Gast.

Applicants' arguments at page 17 of their most recently filed amendment have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

Applicants have merely taken the position that the present claims are patentable because the references relied on above fail teach or suggest the presently claimed subject matter. Such arguments, however, fail to comply with 37 CFR 1.111(b) because they amount to a general

allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

The Examiner has pointed to page and line of the references relied on to support the conclusion that the presently claimed subject matter would have been obvious.

Accordingly, the claims are deemed properly rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

March 28, 2005